K100742

OCT 2 1 2010

510(k) Summary
BLUE NAVIGATION SYSTEM

The summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA and 21 CFR 807.92.

510(k) Submitter:
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Contact Name:
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Date Prepared:
March 5th, 2010.

Proposed Device:

Trade Name:	Exactech GPS Blue Navigation System
Common Name:	Image Guided Surgery System
Classification Name:	Sterotaxic Instruments
Device Class:	II
Product Code:	HAW

Predicate Device:
BLUE NAVIGATION SYSTEM is substantially equivalent to the STRYKER NAVIGATION SYSTEM - KNEE MODULE cleared under 510(k) #K022579 and the TOTAL KNEE SURGETICS NAVIGATION SYSTEM cleared under #K060282.

Device Description:
The BLUE NAVIGATION SYSTEM is an image guided, or navigation, system for orthopedic surgical procedures. It is intended to intraoperatively compute and display information such as distances and angles related to surgical instrument position. It provides this data to help surgeons make decisions, and is not intended to make surgical decisions or replace surgical actions.

The station is composed of an optical localizer system, a computer, and a screen. The localizer tracks in real time the positions of trackers rigidly attached to patient bone or surgical instruments.

The BLUE NAVIGATION SYSTEM is imageless, meaning there is no need for preoperative images (CR or MRI), but is based on intraoperative patient anatomical landmarks that are digitized at the beginning of the procedure by the surgeon. The station uses these landmarks to compute useful information that is displayed on a screen to help surgeons position prosthetic components.

Intended Use:
The BLUE NAVIGATION SYSTEM is intended for use during stereotaxic surgery to help surgeons locate anatomical structures and align endoprostheses.

It is specifically indicated for Total Knee Arthroplasty.

Contraindications:
The surgeon needs to determine if a patient's condition is appropriate for treatment including the BLUE NAVIGATION SYSTEM. Advanced osteoporosis and a dysplastic or stiff hip joint are examples of conditions precluding use of the BLUE NAVIGATION SYSTEM.

Comparison of Technological Characteristics:
The BLUE NAVIGATION SYSTEM shares the same main components with predicate devices: a computer, a display screen, a 6D optical localizer system, localized trackers rigidly attached to patient bone and surgical instruments, , and a localized pointer also used to digitize intraoperative anatomical landmarks.

Both the BLUE NAVIGATION SYSTEM and the predicate devices intraoperatively digitize anatomical patient landmarks with a localized pointer in order to model patient anatomy.

The main technological difference between the BLUE NAVIGATION SYSTEM and the predicate devices is the BLUE NAVIGATION SYSTEM station is smaller and attached to the OR table, making use of a dedicated sterile drape necessary. Any differences in technology do not raise questions or issues regarding safety and effectiveness of the BLUE NAVIGATION SYSTEM.

Performance Testing:
BLUE NAVIGATION SYSTEM was tested in a non-clinical setting (bench testing and anatomical testing) to assess that no new safety and effectiveness issues were raised in the device. Analyses show that the accuracy and performance of the system was adequate for its intended use and not reduced in comparison the predicate devices.

In conclusion, the BLUE NAVIGATION SYSTEM is substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

Blue Ortho
% Mr. Anthony Boyer
President
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38700 La Tronche
France

OCT 2 1 2010

Re: K100742
Trade/Device Name: Blue Navigation System
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic instrucment
Regulatory Class: II
Product Code: OLO, HAW
Dated: October 11, 2010
Received: October 12, 2010

Dear Mr. Boyer:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act

or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for use

510(k) Number: K100742
Not know yet.

OCT 2 1 2010

Device Name:
Blue Navigation System

Indications For Use:
The BLUE NAVIGATION SYSTEM is intended for use during stereotaxic surgery to aid the surgeon in locating anatomical structures and aligning the endoprostheses with the anatomical structures.

It is specifically indicated for Total Knee Arthroplasty.

Prescription Use ___X____ **AND/OR** **Over-The-Counter Use** _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Neil R. P. Ogden for mxn
(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K100742